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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,076	07/07/2003	Steven M. Ruben	PZ034P1C2	8540

22195 7590 09/21/2006

HUMAN GENOME SCIENCES INC.
INTELLECTUAL PROPERTY DEPT.
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EXAMINER

DANG, IAN D

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/613,076

Applicant(s)

RUBEN ET AL.

Examiner

Ian Dang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-48 is/are pending in the application.
- 4a) Of the above claim(s) 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This office action is in response to the amendment and response filed on 07/03/2006. Claims 29, 34, and 43 have been amended and claim 48 has been withdrawn. Claims 25-47 are pending and under examination.

Claim Objections

The amendments to claims 29, 34 and 43 have corrected the informalities. The objections to the claims have been obviated and are withdrawn.

Rejections Maintained

Applicant's arguments and evidence filed on July 03, 2006, have been fully considered but they are not persuasive.

35 USC § 101/112

The rejection of claims 25-47 under 35 U.S.C. 101/112 is maintained.

- Applicant argues that the asserted utilities listed in the specification for HFXHC41 are not based solely on sequence homology to CD 44 and cartilage link protein.

The specification provides evidence that that the two link domains of HFXHC41 protein have been demonstrated to be involved in HA binding and tissue distribution.

Although HFXHC41 encodes for the two link domains, the other part of the polypeptide has not been characterized. It may be that this part prevents HFXHC41 binding to HA or interacts with a protein that prevents it from binding to HA.

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- Furthermore, Applicants argue that past filing date publications have confirmed that BRAL1 or HAPLN2 sequences corresponding to HFXHC41 is expressed in the adult brain and BRAL1 mRNA was detected in neuronal cells of the cerebellum, spinal cord, olfactory bulb, cerebral cortex, hippocampus, and brainstem. Oohashi et al. reports biochemical and immunohistochemical observations suggest that Bral1 binds to HA as expected from its homology to cartilage link protein-1 and other HA-binding molecules.

Although HFXHC41 is expressed in numerous parts of the brain, its function is still uncharacterized. It is expressed in neuronal cells but has activities similar to connective tissues such as cartilage link protein-1 and HA-binding molecules. Its biological activities remain to be characterized.

- Applicants argue that the specification recites that elevated" expression of this gene product in regions of the brain indicates it plays a role in normal neural function. Potentially this gene is involved in synapse formation, neurotransmission, learning, cognition, homeostasis, or neuronal differentiation or survival."

The increased expression of the HFXHC41 polypeptide in normal neural function is not unique to it. A large number of proteins has the same expression pattern and can have similar roles.

- Applicants allege that the specification teaches that the compositions of the claimed invention are useful for the detection, treatment, and/or prevention of neurodegenerative disease states, behavioral disorders, or inflammatory conditions." In addition, Applicants argues that the identification of repetitive CA repeats within the BRAL1 and BCAN genes would facilitate the investigation of these genes involved in inherited schizophrenia.

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Although Applicants suggest that HFXHC41 is “potentially” in several neurophysiologic illnesses, Applicants have not provided any credible evidence. This observation is based on homology between the two proteins and are highly speculative. There is no definite evidence that the CA repeats present in the HFXHC41 polypeptide has a role in any neurological illnesses.

- Applicants argue that all that is required is that there is a reasonable correlation between the biological activity and the asserted utility (see *Nelson v. Bowler*, 626 F.2d at 857). The disclosed utilities for HFXHC41 polypeptides can be used to generate antibodies for diagnosing, treating, and/or preventing schizophrenia.

However, Applicants have not provided any evidence for the role of HFXHC41 in Schizophrenia besides suggesting its expression in neuronal cells.

- Finally, the disclosed utilities for HFXHC41 polypeptides are substantial and credible as “the general rule [is] that the treatments of specific diseases or conditions meet the criteria of 35 U.S.C. 101.

Arguments in the absence of evidence are not persuasive. The rejection is maintained.

35 USC § 112 (first paragraph)

The rejection of claims 25, 27-38 under 35 U.S.C. 112 is maintained.

Applicants argue that the specification as filed provides support for antibodies binding at least 30 or 50 contiguous amino acids disclosed on pages 219-220, paragraph [0661] and page 96, paragraph [0253].

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Although Applicants have indicated that several parts of the specification that can provide support for the new matter, they do not provide specific support for an antibody binding at least 30 or 50 contiguous amino acid residues specific for SEQ ID NO:48. The rejection for new matter is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
September 14, 2006


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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